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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,766	06/20/2002	Martinas Kuslys	112843-043	2286
29157	7590	01/31/2006	EXAMINER	
BELL, BOYD & LLOYD LLC P. O. BOX 1135 CHICAGO, IL 60690-1135			HINES, JANA A	
			ART UNIT	PAPER NUMBER
			1645	
DATE MAILED: 01/31/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/088,766

Applicant(s)

KUSLYS ET AL.

Examiner

Ja-Na Hines

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 November 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3,4,6-10 and 12-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6-10 and 12-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 7, 2005 has been entered.

### ***Amendment Entry***

2. The amendments filed August 5, 2005 and November 7, 2005 have been entered. The examiner acknowledges the amendments to the specification. Claims 1, 6, 10, 12, 13 and 20 have been amended. Claims 2, 5 and 11 have been cancelled. Claims 1, 3-4, 6-10 and 12-20 are under consideration in this office action.

### ***Withdrawal of Rejections***

3. The following rejections have been withdrawn in view of applicants' amendments and arguments:

- a) The obviousness-type double patenting rejection over claims 1-10 and 12-20; and
- b) The rejection of claims 1-10 and 12-20 under 35 U.S.C. 103(a) as being unpatentable over JP-002158762.

***Response to Arguments***

4. Applicant's arguments with respect to claims 1, 3-4, 6-10 and 12-20 have been considered but are moot in view of the new ground(s) of rejection.

***New Grounds of Rejection***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1,3,4,6-10 and 12-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims are drawn to a composition for an infant formula and an infant formula comprising: casein protein, a milk protein that has a level of 5% or more of amino acid tryptophan, hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed, free arginine, free histidine, tryptophan, and a mixture thereof. The written description in this case only sets forth specific

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compositions, therefore the written description is not commensurate in scope with the claims drawn to mixtures thereof. Neither the specification nor the claims teach how to define mixtures thereof. Neither the claims nor the specification teach how to obtain such mixtures. The specification does not include structural examples of mixtures thereof. Thus, the resulting mixture could result in a complex not taught and enabled by the specification.

With the exception of specifically recited composition components, the skilled artisan cannot envision the detailed structure of the mixture thereof, thus conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. An adequate description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. Furthermore, *In The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of molecules falling within the scope of the claimed genus. Therefore only the recited composition and not the full breadth of the claims meet the written description provision of 35 USC 112, first paragraph.

Claim 12 is drawn to a method of treating malnutrition comprising the step of administering a composition containing whey protein, wherein the whey protein is hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed, casein protein, free arginine, free histidine, tryptophan rich milk protein that has a level of 5% or more of amino acid tryptophan, free tryptophan or a mixture thereof. The written description is not commensurate in scope with

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the claims drawn to a method of treating malnutrition. Neither the specification nor the claims teach treating malnutrition. There is no disclosure of patient population would be treated by being administered the above recited composition. There is no teaching that any subject was administered the composition and thereby had their malnutrition treated. There are no experiments or data showing the subjects were treated for malnutrition. Neither the claims nor the specification teach how to treat malnutrition. There is no guidance as to what steps must occur to treat malnutrition.

*Vas-Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

Thus a skilled artisan cannot envision the detailed method of treating malnutrition comprising the step of administering a composition containing whey protein, wherein the whey protein is hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed, casein protein, free arginine, free histidine, tryptophan rich milk protein that has a level of 5% or more of amino acid tryptophan, free tryptophan or a mixture thereof, thus conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. An adequate description requires more than a mere statement that it is part of the invention and a reference to a potential

method of isolating it. The specification is void of any compositions that qualify for the functional characteristics claimed as being capable of treating malnutrition. The written description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, it is deemed that the specification fails to provide adequate written description for the claim and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention. Therefore the full breadth of the claim fails to meet the written description provision of 35 USC 112, first paragraph.

6. Claim 12 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. This is a new matter rejection.

Neither the specification nor originally presented claims provides support for a method of treating malnutrition comprising the step of administering a composition containing whey protein, wherein the whey protein is hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed, casein protein, free arginine, free histidine, tryptophan rich milk protein that has a level of 5% or more of amino acid tryptophan, free tryptophan or a mixture thereof. Applicant did not point to support in the specification for a method of treating malnutrition comprising the step of administering the above described

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composition. Moreover, applicant failed to specifically point to the disclosure of the composition as a means of treating malnutrition. Thus, there appears to be no teaching of a method of treating malnutrition comprising the step of administering the composition.

It appears that the entire specification fails to recite support for the method of treating malnutrition comprising the step of administering a composition. Therefore, it appears that there is no support in the specification. Therefore, applicants must specifically point to page and line number for support of the method of treating malnutrition comprising the step of administering a composition as recited by the amended claim. Therefore, the claim incorporates new matter and is accordingly rejected.

7. Claims 3-4, 6-9 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Dependant claims 3-4 and 6-9 refer to "a composition", however the suggested claim language is to use of the article "the." Therefore the suggested claim language is "the composition."

b) Claim 12 is unclear because it fails to recite what type of patient population can be treated for malnutrition. The claim fails to recite a dosage scheme, route of administration, or an effective amount of composition needed to



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treat malnutrition. Therefore appropriate clarification is required to overcome the rejection.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1, 3-4, 6-10 and 12-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP-002158762 in view of Erdmann et al., EP 97201607.5 (May 27, 1995) the priority document of WO 98/53702 and US Patent 6,787,158. It is noted that US Patent 6,787,158 will be used as the English language version of EP 97201607.5.

Claims 1,3-4, 6-9 and 13-19 are drawn to a composition for an infant formula and an infant formula comprising: casein protein, a milk protein that has a level of 5% or more of amino acid tryptophan, hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed, free arginine, free histidine, tryptophan, and a carbohydrate and lipid source.

JP-002158762 teach a nutritive composition for infants comprising casein, a milk protein that has a level of 5% or more of amino acid tryptophan, whey powder, free arginine, free histidine, and free tryptophan. The composition also contains a lipid and carbohydrate source, just as required by the claims. The

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whey protein is at a 30-40% by weight while the casein protein is at 24-32% by weight. Thus, the amount of each is within the instantly claimed ranges. The nutritive composition can be easily digested and utilized by babies and infants. JP-002158762 teaches a method of making the formula. It is noted that JP-002158762 teach different concentrations for the arginine, histidine, and tryptophan, however limitations such as different concentrations are viewed as limitations not imparting patentability. However, JP-002158762 does not teach the use of hydrolysed sweet whey protein.

Erdmann et al., teach a method for treating a lactic raw material such as sweet whey and a liquid material containing the raw protein material which is useful in an infant or dietetic products and pharmaceutical composition (col. 2 lines 45-57). The lactic raw material can be sweet whey, a lactose-free sweet whey or a hydrolysed sweet whey (col. 2, lines 10-23). The whey obtained from the separation of caseinoglycomacropeptide (GMP) can serve as a protein raw material in the preparation of infant products (col.3, lines 5-8). Thus the hydrolysed sweet whey protein has had the caseino-glyco-macropeptide removed, just as required by the claims. Moreover, the protein product has a very desirable amino acid profile and shows a reduction in threonine and an enrichment in aromatic amino acids such as tryptophan (col. 3, lines 8-11).

Claims 10, 12 and 20 are drawn to methods for producing the infant formula, providing nutrition and treating malnutrition. All the claims recite the active step of administering the composition. JP-002158762 in view of Erdmann et al., clearly teach administering the composition. Thus, the art meets the

limitations of the claims by administering a composition comprising casein protein, a milk protein that has a level of 5% or more of amino acid tryptophan, hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed, free arginine, free histidine, tryptophan, and a carbohydrate and lipid source.

Therefore, it would have been prima facie obvious at the time of applicants invention to modify the composition of JP-002158762 by exchanging the whey powder for hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed and administering the composition. No more than routine skill would have been required to exchange the whey powder which is derived from sweet whey, since the use of a known member of a class of milk proteins or whey products in a composition is not patentable if other whey products from the milk protein class were known to be useful in infant compositions. Furthermore, no more than routine skill is required to adjust the amount of a component of the claimed composition to suit a particular starting material in order to achieve the results taught in the prior art. Moreover there would have been a reasonable expectation of success in the exchange since the art teaches that the hydrolysed sweet whey protein has a very desirable amino acid profile and shows a reduction in threonine and an enrichment in aromatic amino acids as compared to whey.

***Prior Art***

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Georgi et al., (US Patent 5,916,621 and WO 95/17102) teach a hydrolysed sweet whey protein from which the caseinoglycomacropeptide has been removed in a milk baby food composition. Trimbo et al, (US Patent 5,728,678) teach an enteral composition that includes an effective amount of a protein source including whey protein, free amino acids, a lipid source, a carbohydrate source that provide essential and nonessential amino acids.

***Conclusion***


10. No claims allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines 

January 12, 2006



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